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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,003	03/22/2001	David M. Sabatini	50347/002004	5682
21559	7590	09/20/2007		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER KAUSHAL, SUMESH	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 09/20/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

09/817,003

Applicant(s)

SABATINI, DAVID M.

Examiner

Sumesh Kaushal

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 160-177 and 237-246 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 160-177 and 237-246 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 07/05/07 has been acknowledged and fully considered.

Claims 160-177 and 237-246 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/05/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 160-169, 172-175 and 237-246 rejected under 35 U.S.C. 102(b) as being anticipated by Ginaven et al (US 5457041, 1995).

The scope of instant claims encompasses an array comprising a surface having at least 96 locations, wherein each location comprises eukaryotic cells and a feature

comprising one or more defined nucleic acid molecules in a discrete location, wherein the eukaryotic cells are on top of the nucleic acids and the nucleic acid molecules are so affixed to the surface that the cells are capable of becoming become transfected with the one or more defined nucleic acid molecules when the array is maintained for a suitable period of time.

Ginaven teaches a needle array and method of introducing biological substances into living cells using the needle array. The cited art teaches an improved apparatus and methods for introducing biological substances into living plant and animal cells, and, more particularly, to a needle array for carrying a biological substance and to a method of using the needle array to introduce the biological substance carried thereby into such living cells. The cited art further teaches that as used herein, "biological substances" includes, by way of example, DNA, RNA, proteins, nuclei, organelles, vesicles, hormones, metabolites and infectious agents including bacteria, virus, viral particles and virions. The cited art teaches that DNA or RNA are introduced, for instance, into cells for gene expression. The cited art further teaches that the gene expression is also valuable to test the level and fidelity of sense or antisense transcription, translation and ultimately the functionality of the heterologous gene product (see col.1, lines 7-37). The cited art further teaches that biological substances such as RNA and DNA are deposited onto the needle array in a variety of ways including precipitation of the nucleic acid directly onto the structures, or by dipping in a non-toxic nucleic acid carrier suspension, for example a viscous substance such as glycerol or aqueous poly ethylene glycol, prior to delivery. The cited art further teaches that the preferred dimensions for the needle array include but are not limited to an array size up to about 20 by 20 needles (col.4, lines 26-44). Furthermore, a recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art if the prior art has the capability to so perform see MPEP 2114 and *Ex parte Masham 2* USPQ2d 1647 (1987). Thus given the broadest reasonable interpretation the cited art clearly anticipates the invention as claimed.

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Claim 170-171 and 176-177 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginaven et al (US 5457041, 1995) as applied to claims 160-175 and 237-240 above, and further in view of Montgomery et al (Proc Natl Acad Sci U S A. 95(26): 15502-7, 1998) and Fire et al (US 6506559, 2003).

Ginaven is relied upon as described in rejection above. However, Ginaven does not teach the use double-stranded RNA molecule or nucleic acid molecule having a modified base or backbone.

Montgomery teaches the double-stranded RNA mediated genetic interference in *C.elegans*. The cited art teaches a nucleic acid molecule, which encodes double-stranded RNA for RNAi experiments (page 15502, col.2, para.2). The cited art teaches gene-specific probes for insitu hybridization, wherein the probe comprises Digoxigenin (DIG)-labeled single stranded DNA probe (page 15503, col.2, para. 3).

Fire et al teaches a method to inhibit expression of a target gene in a cell in vitro comprising introduction of a ribonucleic acid (double-stranded RNA molecule) into the cell in an amount sufficient to inhibit expression of the target gene. The cited art further teaches that the solutions containing duplex RNAs that are capable of inhibiting the different expressed genes can be placed into individual wells positioned on a micro titer plate as an ordered array, and intact cells/organisms in each well can be assayed for any changes or modifications in behavior or development due to inhibition of target gene activity. The cited art further teaches that the function of the target gene can be assayed from the effects it has on the cell/organism when gene activity is inhibited (see col. 12 lines 46-; col. 26-28 and col. 11-12).

Thus it would have been obvious to one ordinary skill in the art at the time of filing to modify the invention of Ginaven in view of Montgomery or Fire by substituting the nucleic acid molecules with a double-stranded RNA molecule, a nucleic acid molecule that interfere with the function of an endogenous gene or a nucleic acid molecule having a modified base or backbone. One would have been motivated to incorporate such a modification to inhibit the expression of a gene of interest. One would have a reasonable expectation of success, since affixing the nucleic acid sequences on various type of tissue culture supports and transfection of cells using the

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affixed nucleic acid has been routine in the art at the time the instant invention was made. Thus the invention as claimed is *prima facie* obvious in view of cited prior art of record.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUMESH KAUSHAL
PRIMARY EXAMINER